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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,613	01/25/2002	Ralf Geiben Lynn	23659-501	2925

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EXAMINER

CHEN, STACY BROWN

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 01/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/057,613	GEIBEN LYNN ET AL.	
	Examiner	Art Unit	
	Stacy B Chen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) 2,3,5-7,9,11,13-15,20,21,23,25,26,28-34 and 36-48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4,8,10,12,16-19,22,24,27 and 35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendment filed October 29, 2003 is acknowledged and entered. Claims 1-49 are pending. In the amendment filed October 29, 2003, claims 2, 3, 5-7, 9, 11, 13-15, 20-21, 23, 25-26, 28-34 and 36-48 were indicated "canceled", however, there is no statement in the amendment requesting the cancellation of the above named claims. Therefore, the claims are still pending and withdrawn from consideration. Claims 1, 4, 8, 10, 12, 16-19, 22, 24, 27, 35 and 49 are examined.
2. The rejection of claims 5, 6 and 14 under 35 U.S.C. 112, second paragraph, is withdrawn in view of Applicant's amendments. The rejection of claims 1-18, 35 and 36 under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Shapiro (WO 00/52034) is withdrawn in view of Applicant's amendments.

Claim Rejections - 35 USC § 102/103

3. Claims 1, 4, 8, 10, 12, 16-18, 35 and 49 are rejected under 35 U.S.C. 102(b) as being anticipated or in the alternative obvious over Lezdey *et al* (5,532,215), for reasons of record and in view of the following. The amended claims are drawn to a method of inhibiting/decreasing HIV infectivity by contacting an HIV virion with an antithrombin selected from the group consisting of 43 kDa modified antithrombin, R-antithrombin, S-antithrombin, pre-latent antithrombin, a variant thereof, an analog thereof and a combination thereof, and incubating the virion with the antithrombin for a period of time allowing inhibition of infection. New claim 49 is drawn to a method of inhibiting HIV infectivity by contacting an HIV virion with antithrombin

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III. Claim 49 is included in this rejection because antithrombin III is synonymous with antithrombin.

Claims 16-18 are drawn to amounts of antithrombin to be administered. One of ordinary skill in the art would know how to administer the antithrombin, as evidenced by Ledzey which teaches sample dosages of serpin alpha 2-macroglobulin (col. 6, lines 51-57). One would have had a reasonable expectation of success that the ability to determine dosages would have been well within the ability of one of ordinary skill, given that the administration of serine protease inhibitors is well known, as evidenced by Ledzey.

Applicant's substantive argument is primarily directed to the assertion that Ledzey does not teach or suggest any specific antithrombins that are effective in inhibiting HIV proliferation. In response, Ledzey teaches a method for inhibiting HIV proliferation by inhibiting viral replication or killing the viruses on contact via human serine protease inhibitors such as antithrombin (abstract, col. 5, lines 17-25, col. 6, line 31 and col. 3, lines 39-41). Although Ledzey is silent on specific antithrombins, Ledzey teaches that conjugates of heparin and serpins which have active sites can be used in the method of inhibiting HIV proliferation (col. 3, lines 16-19). A conjugate of heparin and antithrombin results in S-antithrombin, and serpins such as antithrombin bind heparin. Therefore, the claims remain rejected.

Claim Rejections - 35 USC § 103

4. Claims 19, 22, 24 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ledzey *et al* (5,532,215) as applied to claims 1, 4, 8, 10, 12, 16-18, 35 and 49 above, and further in view of Hopkins (WO96/10639). The claims are drawn to a method of inhibiting HIV

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infection with an antithrombin selected from the group consisting of 43 kDa modified antithrombin, R-antithrombin, S-antithrombin, pre-latent antithrombin, a variant thereof, an analog thereof and a combination thereof, wherein the antithrombin is expressed by a producer cell comprising the antithrombin DNA. Lezdey fails to teach the expression of antithrombin in a producer cell.

Hopkins teaches modified serine protease inhibitors, including antithrombin (abstract). Hopkins introduces the modified serpin DNA/vector into a host cell and expresses the serpin (pages 17-18). It would have been obvious to express a serpin, such as antithrombin, for use Hopkins' method to treat HIV infection. Gene expression in producer cells and gene therapy (localized expression) are well known procedures for delivery of therapeutic agents. One would have been motivated to use Hopkins gene expression method in Lezdey's method because DNA expression of therapeutic agents was a common method of delivery at the time of the invention, as evidenced by Hopkins. One would have had a reasonable expectation of success that Hopkins' method of gene delivery and expression would work in the method of Lezdey. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

5. No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Papers relating to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 located in Crystal Mall 1. The Fax number for Art Unit 1648 is (703) 308-4426. All Group 1600 Fax machines will be available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Stacy B. Chen, whose telephone number is (703) 308-2361. The Examiner can normally be reached on Monday through Friday from 7:30 AM-4:00 PM, (EST). If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, James C. Housel, can be reached at (703) 308-4027. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SBC

Stacy B. Chen
January 8, 2004

James C. Housel
JAMES HOUSEL 1/12/04
SUPERVISORY PATENT EXAMINER
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